REMARKS

I. PROSECUTION HISTORY AND SUMMARY OF AMENDMENTS

The application as filed included claims 1-37. A preliminary amendment was filed on May 4, 2001 canceling claims 1-37 and adding new claims 38-96. In response to the official action dated April 29, 2003, claims 38-96 were canceled and new claims 97-155 were added. In response to the official action dated March 10, 2004, claims 97-155 were canceled and new claims 156-219 were added. Claims 156-219 were examined in the most recent Office action, dated July 21, 2005.

Claims 156, 158-160, 164-165, 169-170, 174-175, 179-180, 184-185, 189-190, 194-195, 198, 203, 208 and 213 are currently canceled. Claims 157, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-197, 199-202, 204-207, 209-212 and 214-219 are currently amended. No new matter has been added by these amendments. Applicant reserves the right to pursue claims directed to any unclaimed subject matter in related applications, such as continuing applications.

II. THE CLAIMS ARE IN FULL COMPLIANCE WITH 35 U.S.C. § 101

On pages 2-10 of the Office action, the Office rejected claims 156-219 under 35 U.S.C. § 101 for allegedly not being supported by either a specific and substantial utility or a well-established utility. Applicant respectfully traverses and requests that the rejection be withdrawn for the reasons discussed herein.

A. The Claimed Invention has a well established utility.

The present invention relates to a collectin (calcium dependent lectin) polypeptide and polynucleotide that encodes it, and an extensive portion of the Office action is directed to whether or not this invention falls within a genus that has a well established utility.

1. The Applicant have established that the claimed polypeptide is a calcium dependent lectin (collectin).

The present application teaches that the protein of the invention is a calcium dependent lectin (known as a collectin). See, e.g., page 2, lines 17-19. The application explains that the sequences of known collectins were used as part of the experiments to identify and isolate the collectin of the invention. (See, e.g., Examples 1-3.) The application shows that the novel collectin has homology with known collectins. (See Examples 4, 8.) The application teaches that the novel collectin has utilities of the same sorts as known lectins. (See page 47, for example.)

2. Lectins as a class have a well established utility.

The U.S. Patent and Trademark Office has *an entire patent classification* (530/396) devoted to the lectins, the subject matter of the invention. A brief database search on the PTO website indicates that at least 126 patents have been issued under this classification, presumably related to lectin subject matter. The oldest patents were issued more than forty years ago. At least one patent directed to the use of a lectin in a purification matrix was issued more than twenty years ago. (See Patent No. 4,450,104, "Water insoluble gel matrix containing lectin bound to antithrombin," issued in 1984). Other patents relate to therapeutic applications.

These facts alone are sufficient to establish that lectins have well established utilities. Because the claimed invention is a lectin and lectins have well established utilities spanning decades, it follows that the claimed invention also has a well established utility as a lectin, and that one skilled in the art would have understood how to use a new lectin, such as the claimed molecules, for detecting and/or purifying molecules to which they bind and/or for its biological activities towards pathogens.

B. The Claimed Invention Has A Specific and Substantial Utility

Beginning on page 1 of the specification, the claimed polypeptide and polynucleotide is identified as a collectin, and the known, established properties of collectins are described, e.g., anti-bacterial and anti-viral activity. See, e.g., page 1, line 9, to page 2, line 16. Figure 5 shows the alignment of the claimed polypeptide with known collectins, see page 3, lines 23-25. "Courts have routinely found evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for a new compound." M.P.E.P. § 2107.03.

As confirmation of applicant's asserted utility, the applicant submitted a Rule 132 declaration filed in response to the official action dated March 10, 2004, in which the inventor describes experiments that confirm the claimed invention has utility as set forth in the specification. The inventor showed that the claimed collectin is able to bind to various saccharides (carbohydrates) in a calcium dependent manner, a property consistent with C-type lectins, including collectins. The polypeptide as claimed, which comprises the core region corresponding to amino acids 389-547 of SEQ ID NO: 2, was expressed using the methodology referred to in paragraphs 4-5 of the declaration. The collectin polypeptide was prepared and tested in its ability to bind various saccharides in the relative presence and absence of calcium. The results, summarized in the figure of paragraph 9 of the declaration, show that depletion of calcium ions with EDTA prevents the binding between the polypeptide and the saccharides tested. Binding between the expressed collectin polypeptide and various saccharides, in the absence of the calcium chelator EDTA, but not in the presence of EDTA confirms that the expressed collectin polypeptide binds to carbohydrates in a calcium-dependent

manner. This indicates that the claimed polypeptide is a collectin, i.e., a lectin which binds saccharides in a calcium-dependent manner.

Moreover, the declaration demonstrates that the claimed polypeptide has a preference for binding galactose over mannose. Interestingly, the carbohydrate recognition domains of known collectins contain the EPN-E-WND sequence, which has been shown to be important in (1) binding calcium and (2) determining *mannose* specificity. Conserved amino acids in the EPN-E-WND sequence have been identified as important for determining saccharide preference. The difference in saccharide specificity (i.e., galactose over mannose) is an unexpected property. It is rightly characterized as a property that is entirely dependent on the unique sequence of the claimed collectin polypeptide. Accordingly, the data discussed by the inventor confirm that the claimed polypeptide comprises a collectin and possesses utility(ies) associated with the same, and the rejection should be withdrawn.

Several of the publications of record also support the designation of the claimed subject matter as a collectin. For example, Hoppe and Reid (Ref. C30; Protein Science 3:1143-58 (1994)), describe the common structure of collectins (at pages 1144-1149), carbohydrate recognition (at pages 1149-1150) and binding of collectins to bacteria and viruses (at pages 1150-1152), and the Hoppe description is consistent with the collectin claimed in the present application and described in the specification.

The fact that the claimed protein is a member of the collectin family is further evidenced by acceptance of the inventor's publication in a prominent journal. Ohtani et al., (J. Biol. Chem. 276:44222-44228, 2001), a copy of which was provided to the Office in response to the official action dated October 28, 2004, describe a collectin, CL-P1, that can also function as a scavenger receptor. Ohtani et al. further describe the ability of CL-P1 to form an oligomeric structure and its ability to bind and induce phagocytosis of bacteria and yeast as well as oxidized LDL. The fact that the prominent journal, Journal of Biological Chemistry, accepted and published this manuscript is evidence that scientists in the field would regard the molecule as a collectin.

The art accepts that the CL-P1 is a collectin even though it has a transmembrane domain, in contrast to the classical collectins which are soluble and secreted proteins. Van de Wetering et al. (Eur. J. Biochem., 271:1230-1249, 2004) describe members of the collectin family and their functions in innate immunity. One of the collectin family members, CL-P1 (collectin placenta-1), shares 100% identity to the claimed polypeptide sequence over 547 amino acids. CL-P1 is a membrane-bound collectin that is involved in the uptake of oxidized LDL particles. It has also been determined that CL-P1 recognizes *E. coli* and *S. aureus* (Lu et al., Biochim. Biophys. Acta, 1572:387-400, 2000). Of note is the fact that CL-P1 preferentially binds galactose over mannose. The same binding properties are found in the claimed polypeptide sequence (see Rule 132 declaration, page 4).

The art accepts that the full length CL-P1 sequence functions as a collectin. The smaller molecule claimed in the instant application has an active domain that is sufficient to maintain galactose binding in a calcium-dependent manner, and thereby preserves a well-established utility of a collectin.

To have a specific utility, the claimed species, e.g., a protein, possesses a utility that is specific, i.e., one not common to **all** proteins. The claimed species comprises a protein that binds saccharides in a calcium dependent manner. Not all proteins have such characteristics, which means the claimed species has a specific utility that satisfies the utility requirement of the statute. Even more specific, the claimed polypeptide exhibits a preference for galactose that is not shared by many other collectins.

The claimed species is also substantial. To be substantial, the claimed subject matter must have a "real world" use. The evidence and the reasoning provided herein (and previously) establish that collectins in general, and the claimed collectin subject matter in particular, have substantial utility.

C. Responses to specific issues raised by the examiner.

The examiner suggests, without citing any authority that the specification is defective for failing to identify "the unique function" of the claimed collectin that arise from its novel structure. The statute requires a utility, and the Patent Office has indicated that a specific utility is required (e.g., a utility other than as a source of amino acids that would apply to any protein). There is, however, no authority for the proposition that every invention must have a "unique" utility. If the examiner persists in this objection, the applicant request the citation of legal authority for purposes of a complete record for appeal.

Moreover, as explained above, the galactose binding preference of the claimed collectin (which must be attributed to its structure) differentiates it from known collectins with mannose binding preference.

Moreover, later in the office action, the examiner cites evidence that each collectin exhibits a distinct profile of organisms recognized thereby. In other words, the examiner is asserting that the very uniqueness that is, on the one hand, desirable for utility is, on the other hand, a factor that weighs against a finding of utility! These inconsistent positions cannot be reconciled. For patent purposes, the proper way to interpret this evidence of "distinct profile of organisms" is that *each collectin is useful* for its ability to recognize one or more organisms. The Lu reference supports, rather than negates, a finding of utility for the claimed collectin in particular and collectins in general.

The examiner also suggests that one of ordinary skill would not be able to identify a well established utility for the novel collectin of the invention. The very nature of "well established" means that one of ordinary skill would appreciate its existence, as explained above in part A. If the

examiner's position is that one skilled in the art could not perform carbohydrate binding studies or pathogen binding studies as described in the prior art or the application, to confirm well established utilities, the applicant requests an explanation of what details were beyond the ability of one of ordinary skill and beyond the teachings in the application. The examiner's assertions that the function would be expected to be related to other collectin family members in general terms, but that this related function does not suffice to confer the well established utility of lectins on the claimed molecule, is difficult to understand. It is especially difficult to understand when the applicant hase provided *evidence to confirm* that the claimed molecule has collectin functions.

At page 7, the examiner dismisses as "not probative" the evidence supplied by the applicant after the filing date of the application. This evidence demonstrates that the claimed molecule has properties of a collectin – as taught in the application. The Patent Office's reviewing courts have long recognized post-filing date evidence as probative for these purposes. See, e.g., In re Brana, 34 USPQ2d 1436 (Fed. Cir. 1995).

D. Conclusion

For all of these reasons, the rejection is improper and should be withdrawn.

III. THE REJECTIONS UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

A. The Specification Teaches How To Use the Claimed Invention

On page 10 of the Office action, the Office rejected claims 156-219 under 35 U.S.C. § 112, first paragraph, alleging that the invention was not supported by either a specific or substantial asserted utility or a well-established utility for the reasons described in relation to the § 101 rejection. Applicant respectfully traverses. The rejection should be withdrawn for the same reasons as those described in the preceding section.

The rejection also is based, at least in part, on the alleged unpredictability of predicting function based on structural similarity. The experimental evidence made of record by the applicant largely renders this issue moot, by confirming that the claimed polypeptide has collectin functions. When a patent examiner questions the operability of an invention under §112, first paragraph, an applicant is permitted to use post-filing date evidence to refute such assertions. See, e.g., *Gould v. Quigg*, 3 USPQ2d 1302, 1305 (Fed. Cir. 1987); *In re Marzocchi,* 169 USPQ 367, 370 n. 4 (CCPA 1971); *In re Pottier*, 153 USPQ 407, 408 n.2 (CCPA 1967).

B. The Claimed Subject Matter Is Adequately Described

On page 14 of the Office action, the examiner rejected claims 158, 162, 164, 167, 169, 172, 174, 177, 179, 182, 184, 187, 189, 191, 192, 194, 197, 203, 206, 213, 216 and 219 under 35

U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant respectfully traverses and submits that the rejection should be withdrawn.

At least part of the rejection was based on alleged inappropriateness of hybridization language to define variants of the invention. Such limitations serve to define the structure of a molecule in relation to a specified molecule, and are cited with approval in the PTO's own written description training materials.

Claims 158, 164, 169, 174, 179, 184, 189 and 194 have been canceled rendering the rejection moot with respect to these claims. Claims 162, 164, 167, 172, 177, 182, 197 and 219 have been amended to explicitly recite those polynucleotides or polypeptides set forth in the specification. Claims 203 and 213 are directed to a vector and host cell comprising the nucleic acid of amended claim 177.

C. The indefiniteness rejection is rendered moot.

Claim 191 was rejected for not having proper antecedent basis for "polypeptide." Amended claim 191 corrects the antecedent basis issue. Accordingly claim 191 and dependent claims 206 and 216 are adequately described in the specification.

D. Conclusion

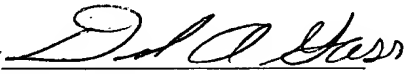
Thus, in view of the above, claims 162, 164, 167, 172, 177, 177, 182, 191, 197, 203, 206, 216 and 219 are adequately described in the specification and the rejection should be withdrawn.

CONCLUSION

Applicant submits that all of the outstanding rejections have been overcome and that the claims of the application are now in condition for allowance. Applicant requests an early notification thereof. The Examiner is invited to contact the undersigned with any questions, comments or suggestions relating to the referenced patent application.

Dated: December 21, 2005

Respectfully submitted,

By 

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